REMARKS

Claims 7 and 13 have been amended in order to clarify the inventive subject matter. Claims 1-16 stand rejected. In view of the amendment and the remarks below, reconsideration is respectfully requested.

Objection to the Abstract

The Examiner has objected to the abstract for being too short in length. Applicant has herein submitted a new abstract in compliance with the requirements. Withdrawal of the objection is respectfully requested.

Objection to the Drawings

The Examiner has objected to the drawings as failing to comply with 37 C.F.R. §1.84(p)(4) because reference character 12 has been used to designate both the "stent" and "the outer surface".

In response thereto, Applicant has amended the specification, specifically the paragraph extending from page 5, line 25 to page 6, line 2. Applicant has amended the specification so that reference number 12 is used only to refer to the stent. Withdrawal of the objection is respectfully requested.

The Examiner has further objected to Figure 8 because it has not been designated at prior art. Applicant herein attaches a revised Figure 8 with such designation. Withdrawal of the objection is respectfully requested.

The Examiner has further objected to the drawings as failing to comply with 37 C.F.R. §1.84(p)(4) because reference characters 10 and 12 have both been used to designate "the stent".

Applicant has amended the paragraph on page 6, lines 7-14 and the paragraph on page 8, lines 4-9 in response thereto. Applicants have amended the paragraphs so that the stent is only referred to by reference numeral 12 of the figures. Withdrawal of the objection and reconsideration is respectfully requested.

The Examiner has further objected to the drawings for failing to comply with 37 C.F.R. §1.84(p)(5) as reference numbers 11 and 13 have not been included thereon. Applicant submits the attached new drawings in response to the rejection including reference numbers 11 and 13. Withdrawal of the objection is respectfully requested.

Rejections under 35 U.S.C. §112

The Examiner has rejected claim 7 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

More specifically, the Examiner points out that there is insufficient antecedent basis for the terms said inner surface, said exterior surface, and the longitudinal stent axis in lines 6 and 7, respectively.

Applicant has amended the claims to properly recite these elements in accordance with the Examiner's suggestion. Withdrawal and reconsideration is respectfully requested.

Claim Objections

The Examiner has objected to claim 14 under 37 C.F.R. §1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. More specifically, the Examiner alleges that, "it is common knowledge in the art that non-stretched polyteterafluoroethylene has an absence of node and fibril structure."

Applicant respectfully disagrees. It is possible that non-stretched polytetrafluoroethylene may have a node and fibril structure. Such structures may be formed in the absence of stretching by actinic radiation, or other texturizing techniques commonly known in the art.

Claim 14 therefore further limits the subject matter by specifically requiring an absence of node and fibril structure in the non-stretched polytetrafluoroethylene. The objection is respectfully traversed. Withdrawal and reconsideration is respectfully requested.

Rejections under 35 U.S.C §102

The Examiner has rejected claims13-16 under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 6,156,064 to Chouinard. More specifically, the Examiner states:

> Chouinard discloses an endoprosthesis, which includes all limitations recited in the claims. Chouinard discloses a radially tubular stent and stent cover (col. 1, lines 8-12; col.2, lines 45-47; col.3, lines 29-33), the stent having an interior and an exterior surface (col. 2, lines 41-44) and a porous non-stretched polytetrafluoroethylene stent cover (col. 2, lines 62-67; col. 3, lines 1-2, 48-50) on both interior and exterior surfaces (col. 3, lines 24-29).

Chouinard discloses a PTFE membrane used in a stent-graft device. The membrane disclosed in Chouinard is not stretched, and therefore does not have a porous structure as in the presently claimed invention.

The composite device of Chouinard has a graft layer which has a permeability ranging from about 50 cc/cm^2/min. to about 5000 cc/cm^2/min. The membrane layer is on the other hand, much less permeable, having permeability in the range of 0 cc/cm^2/min. to 100 cc/cm^2/min. (see Chouinard col.2 lines 60-67). The PTFE membrane of Chouinard is in fact used as an impermeable layer in the composite stent-graft, and is designed to make the stent graft more fluid tight.

The graft layer of Chouinard is conventionally stretched PTFE with its expected porosity and the membrane is designed to "limit permeability". (Col. 9, line 8). While Chouinard's membrane does have permeability ranges (which indicate its low porosity), the membrane of Chouinard is not a porous PTFE substrate having distinct pores as claimed in the present invention. Applicant has amended claim 13 to more clearly describe the subject matter. Applicant has indicated that the PTFE substrate is porous and has distinct voids interconnected between pockets of PTFE. Support for this is found in Figure 7 of the present application and at page 7, lines 8-13. Chouinard does not disclose this PTFE substrate structure.

Chouinard in fact attempts to make the membrane limit permeability and make it more fluid tight. This can be seen in Chouinard at column 9, lines 30-35 where it is stated:

> A membrane may also be formed by impregnating a porous graft with a polymer. The polymer becomes integrated in the graft interstices, resulting in a graft-membrane which has substantially lower permeability than the graft starting material.

Chouinard therefore does not disclose a membrane with voids as presently claimed. Chouinard in fact teaches away from this objective as it teaches impregnating the membrane in order to lower its permeability. Chouinard attempts to eliminate its pores, while the present invention is directed to providing pores, or voids in the PTFE. The rejection is respectfully traversed.

In view of the amendment and remarks above, withdrawal of the rejection and reconsideration is respectfully requested.

Rejections under 35 U.S.C. §103

The Examiner has rejected claim 14 under 35 U.S.C. 103(a) as being unpatentable over Chouinard in view of U.S. Patent No. 6,235,377 to Dillon. More specifically, the Examiner states:

> Dillon teaches formation of nodes and fibrils caused by stretching or expansion (col.2, lines 1-22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dillon's teaching of node and fibril formation by stretching with Chouinard's non-stretched stent cover, in order to not stretch the polytetrafluoroethylene, to prevent the formation of nodes and fibrils.

Applicant has addressed the relevance of Chouinard above. Based on the amendment and the remarks above, it is submitted that Chouinard fails to anticipate, teach, or suggest the present invention. Its combination with Dillon does not cure any of the deficiencies of Chouinard pointed out above.

In fact, as stated by the Examiner, Dillon teaches conventional stretching of PTFE to form ePTFE. Dillon therefore has the conventional node-fibril structure of ePTFE. The Examiner is postulating that the formation of a node and fibril structure by stretching proves that it is obvious to form a porous structure without stretching and without node and fibrils, i.e., that Dillon is being cited to prove the obviousness of something not disclosed in Dillon. Applicant believes this to be an improper rejection and withdrawal is respectfully requested.

The Examiner has further rejected claims 1-4 and 6 under 35 U.S.C. §103(a) as being unpatentable over Chouinard in view of U.S. Patent No. 4,945,125 to Dillon and in further view of U.S. Patent No. 6,143,675 to McCollam et al. More specifically, the Examiner states:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine MCCollam's teaching of heating a composite to form pores, with Dillon's teaching of siloxane/ polytetrafluoroethylene IPN formation with high temperature heating, with Chouinard's siloxane/polytetrafluoroethylene stent cover in order to cure the siloxane and form a porous stent cover.

Applicant respectfully disagrees. As stated above, the membrane of Chouinard is impregnated with a polymer in order to make the membrane less porous. McCollam similarly

discloses the formation of a non-expanded PTFE layer by sintering. Sintering is defined as heating PTFE above its melting point at col. 3, lines 18-23. The PTFE layer however, is formed of an aggregate of particles "comprising granular-type PTFE wholly or partially made-up of granular-type particles." (See column 3, lines 9-17 of McCollam).

The PTFE layer in McCollam is formed by a method where aggregate particles are heated to form a PTFE layer by melt fusion. The composite in McCollam is designed to provide an open porous structure which allows liquid to be received into the structure, and is used as a filter. (See abstract of McCollam, column 3, line 65 to column 4, line 3.)

Dillon et al. discloses a microporous membrane characterized by nodes interconnected by fibrils which is **formed by stretching or expanding** the PTFE. Chouinard discloses a membrane which is designed to limit permeability (see column 9, lines 9-10). The membrane of Chouinard is not stretched. The membrane of Chouinard however, is impregnated with a polymer to make it less porous. One would not look to combine a filter material such as that in McCollam with a membrane designed to limit porosity as provided in Chouinard. One would further not look to combine either reference with Dillon which teaches stretching polytetrafluoroethylene to form ePTFE.

Specifically, one would not combine the membrane in Chouinard which is designed to limit permeability with the filter membrane of McCollam. The two designs have the opposite objects as their goal. The combination is therefore improper.

The Examiner has therefore failed to make a *prima facie* case of obviousness under 35 U.S.C. Section 103. Withdrawal of the rejection and reconsideration is respectfully requested.

The Examiner has rejected claim 5 under 35 U.S.C. §103(a) as being unpatentable over Chouinard in view of Dillon and in further view of McCollam et al. and in further view of Kipke et al. (Publication No. US2001/0031978A1). In the interest of brevity, Applicant will not

reiterate the arguments with regard to the combination of Chouinard in view of Dillon and in further view of McCollam with regards to obviousness addressed above. Based on Applicant's remarks, however, it is submitted that the combination of references in further view of Kipke still fail to disclose the invention as claimed. The rejection of claim 5 is therefore respectfully traversed. Withdrawal and reconsideration is respectfully requested.

The Examiner has rejected claims 7-9 under 35 U.S.C. §103(a) as being unpatentable over Chouinard in view of Dillon (U.S. Patent No. 4,945,125). More specifically, the Examiner states:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dillon's teaching of method of making a siloxane/polytetrafluoroethylene interpenetrating network with Chouinard's siloxane/polytetrafluoroethylene stent cover in order to form a porous cover with increased strength.

Applicant again respectfully disagrees. As addressed above, Chouinard teaches the impregnating of a PTFE non-stretch membrane in order to make the membrane less porous. Dillon discloses forming an IPN and stretching to form ePTFE.

One would not look to combine the non-stretched membrane of Chouinard with the stretched PTFE of Dillon. If however, they were combined, the combination would not arrive at the presently claimed invention of claim 7. As previously mentioned, Chouinard provides for the impregnating of PTFE with a polymer in order to make it less permeable. Claim 7 provides a "porous polytetrafluoroethylene by extracting siloxane form an inter-penetrating network of siloxane and polytetrafluoroethylene." A porous PTFE by such extraction is not disclosed in Chouinard.

The Examiner has therefore failed to make a case of *prima facie* obviousness as one would not look to combine the references, and even if combined, the combination would not arrive at the present invention as claimed. Withdrawal and reconsideration of the rejection is

respectfully requested.

The Examiner has rejected claims 10 and 11 under 35 U.S.C. §103(a) as being unpatentable over Chouinard in view of Dillon as applied to claim 7 above, and further in view of Edwin et al. (US Patent No. 6,053,943). More specifically, the Examiner states:

> Chouinard in view of Dillon disclose the invention substantially as claimed. Chouinard in view of Dillon does not however, disclose fixation by a particular adhesive, or fixation by a particular adhesive, or fixation by welding. Edwin teaches a radially expandable stent having a stent cover adhered to stent by an adhesive selected from the group consisting of polyurethane's, epoxies, cyanoacrylates, polyamides, polyimides, and silicones in order to bond the stent to the stent cover. Edwin teaches a method of bonding the stent to the stent cover by welding at a temperature above polytetrafluoroethylene's sintering temperature.

Applicant refers to the arguments with regard to claims 7-9 above. Edwin fails to disclose any of the deficiencies mentioned with regard to the rejection of claims 7-9. The rejections of claims 10-11 in view of Edwin also therefore fail to make a *prima facie* case of obviousness. Withdrawal and reconsideration is requested.

The Examiner has further rejected claim 12 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,143,675 to McCollam in view of U.S. Patent No. 5,908,923 to Dillon. More specifically, the Examiner states:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dillon's teaching of IPN formation with siloxane, with McCollam's method for forming a porous polytetrafluoroethylene structure in order to increase strength in elasticity.

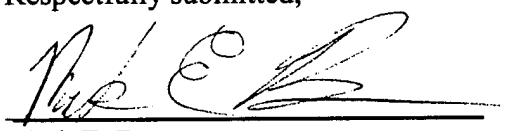
McCollam as previously mentioned discloses a composite laminate which is used in filter devices, for oiling and cleaning high temperature fuser rolls in a photocopying machine, or as a filter. (see Abstract of McCollam) Dillon teaches an ePTFE containing siloxane. McCollam

further comprises an ePTFE layer with the non-expanded PTFE formed by sintering. McCollam provides the advantages of an ePTFE layer by actually providing an ePTFE layer. Dillon similarly expands stretches the polytetrafluoroethylene to form ePTFE.

The present invention is directed to providing the advantage of a stretched polytetrafluoroethylene without expanding the substrate. One would not look to combine McCollam and Dillon to come to the results of the present invention. Such a combination is improper as hindsight. Withdrawal of the rejection and reconsideration is respectfully requested.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number set forth below.

Respectfully submitted,



Mark E. Baron
Reg. No. 46,150
Attorney for Applicant

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700

VERSION OF AMENDMENT WITH MARKING SHOWING CHANGES MADE

ABSTRACT:

~~An endoprosthesis device and method of making it are disclosed. More particularly, the endoprosthesis is a porous PTFE article used in conjunction with a stent.~~

A porous polytetrafluoroethylene substrate is used in an endoprosthesis device. An elongate radially expandable tubular stent is also included with the porous PTFE substrate, and form the endoprosthetic device. A method of making the porous polytetrafluoroethylene entails a novel method including siloxane in PTFE and thereafter removing the siloxane to form the porous structure. The PTFE structure does not have nodes and fibrils.

IN THE SPECIFICATION:

Please replace the paragraph on page 5 from line 25 to page 6, line 2 with the following paragraph:

"Fig. 3 illustrates generally at 10 an intraluminal device in the form of a stent 12 as shown in fig. 1 having a cover 14 on the outer surface of the stent 12 and liner 16 on the inner surface, both of which may be of the porous structure shown below in fig. 7. The stent may optionally have only a cover 14 as shown in fig. 5, or only a liner 16 as shown in fig. 6, or both as shown in fig. 3. In a preferred embodiment, the stent has both a cover 14 and a liner 16. The liner, cover, or both, will be referred to hereinafter collectively as a cover or covering. The cover provides an effective barrier about the stent 12 preventing excessive cell or tissue ingrowth or thrombus formation through the expanded wall of the stent 12."

Please replace the paragraph on page 6, lines 7-14 with the following paragraph:

"Fig. 1 is a more detailed illustration of stent ~~10~~ 12 and shows generally an elongate tube. The body of stent 12 defines an opposed interior surface 11 and an exterior surface 13 and is

formed of a generally open configuration having a plurality of openings or passages provided for longitudinal flexibility of the stent as well as permitting the stent to be radially expanded once deployed in the body lumen. Both the interior surface 11 and the exterior surface 13 may have the porous PTFE covering of the present invention. On the interior surface the covering is referred to as the liner 12 as shown in Fig. 1 and on the exterior surface it is referred to as a cover 14 as shown in Fig. 1."

Please replace the paragraph on page 8, lines 4-9 with the following paragraph:

"As discussed above, the stent may be covered on the interior surface 11 of the stent ~~10~~ 12, the exterior surface 13 of the stent ~~10~~ 12. or both. Preferably, the stent ~~10~~ 12 is covered on both the interior 11 and the exterior 13 surfaces of the stent ~~10~~ 12. Having the entire surface of the stent ~~10~~ 12 covered with the porous PTFE of the present invention provides an effective barrier about the stent ~~10~~ 12 preventing excessive cell or tissue growth, or thrombus formation through the expanded wall of a tubular stent ~~10~~12.

IN THE CLAIMS:

7. A method of covering an endoprosthesis device comprising the steps of:

providing an elongate radially expandable tubular stent;

providing a porous polytetrafluoroethylene by extracting siloxane from an interpenetrating network of siloxane and polytetrafluoroethylene;

forming a stent cover from said porous polytetrafluoroethylene; and

applying said stent cover to an ~~said~~ interior surface~~, said~~ and exterior surface, or both of said stent wherein said stent cover extends along ~~the~~ a longitudinal stent axis.

13. An endoprosthesis device comprising:

an elongate radially expandable tubular stent having an interior surface and an exterior surface extending along a longitudinal stent axis; and

a stent cover on said interior surface, exterior surface or both, which is formed of a

porous polytetrafluoroethylene;

wherein said porous polytetrafluoroethylene comprises a non-stretched porous structure having voids intermeshed between pockets of PTFE.